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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/558,442

09/12/2006

Bert Sutter

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06/08/2009

AKERMAN SENTERFITT

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WEST PALM BEACH, FL 33402-3188

EXAMINER

LEE, BENJAMIN HYOUNGSOL

ART UNIT

PAPER NUMBER

4137

MAIL DATE

DELIVERY MODE

06/08/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/558,442	<b>Applicant(s)</b> SUTTER ET AL.	
	<b>Examiner</b> BENJAMIN LEE	<b>Art Unit</b> 4137	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-2, 7, 10-13 is/are rejected.
- 7) ☒ Claim(s) 1-13 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 November 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/3/2006</u> .  | 6) <input type="checkbox"/> Other: _____                          |

***DETAILED ACTION***

***Claim Objections***

1. Claims 1-13 are objected to because of the following informalities: A proper transitional phrase (e.g. comprising, consisting, etc.) to claim 1 is suggested to provide a clear demarcation between the preamble and body of the claim. Appropriate correction is required.
2. Claims 3-6, 8, 9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claim 4 recites the limitation "the insulating cladding". There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. **Claims 1, 7, 10 and 12** are rejected under 35 U.S.C. 103(a) as being unpatentable over PG Pub. No. 20030144656 to Ocel, et al., in view of U.S. Patent No. 5,944,715 to Goble, et al.

**As to claim 1**, Ocel teaches an instrument capable of the unipolar ablation of heart tissue, by directing the instrument at heart tissue after an incision has been made, comprising:

- an electrically conductive tube 60 electrically insulated on its outer surface with insulating layer 62 (Fig. 3, ¶ 39), wherein the tube is a rigid shaft tube since the shaft 22 is described as “relatively rigid” (¶ 34);
- an electrical connector 28 on the proximal end of the tube which is electrically conductively connected to said tube (¶ 33);
- a rinse connection 26 on the proximal end of the tube which is in fluid communication with a lumen 50 of the tube (Figs. 2 & 3, ¶ 35);
- and an electrode 44 mounted into the distal end of the tube (Fig. 4A-B) which is inherently connected electrically conductively to the tube, and features multiple discharge openings 52 which is in communication with the lumen 50 of the tube (Fig. 6, ¶ 36).

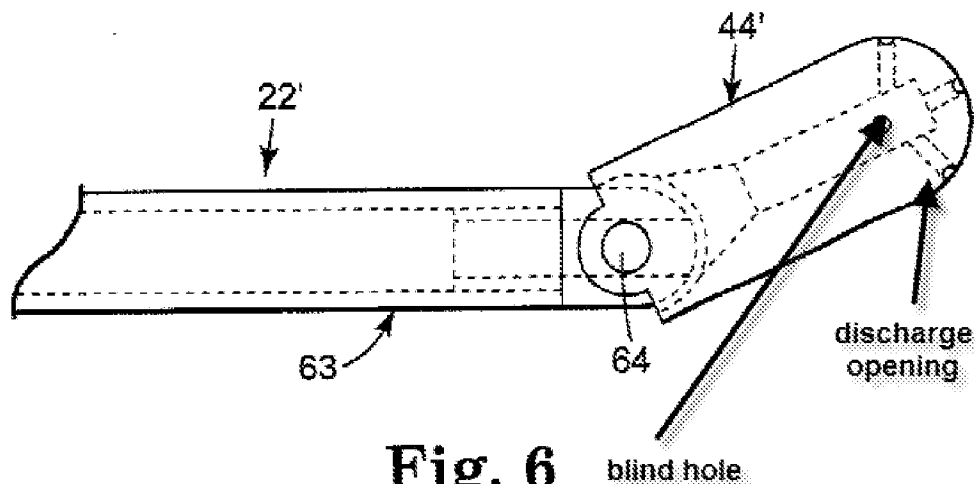
Ocel does not expressly teach that the electrode is connected detachably with the distal end of the shaft tube. However, Goble teaches an electrosurgical instrument with detachable electrodes. Each electrode configuration E1-E5 has unique properties

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for specific applications. For example, electrode configuration E2 is useful when access is needed to remote areas of a joint cavity (col. 11, line 65- col. 2, line 2) and electrode configuration E5 is useful for surgeries requiring working channel introduction (col. 11, lines 50-53).

It would have been obvious to one of ordinary skill in the art at the time of the invention to make the electrode detachable from the distal end of the shaft tube in order to use the device of Ocel in situations where the electrode properties must be changed depending on the particular application (Goble, col. 11, line 65- col. 2, line 2; col. 11, lines 50-53).

**As to claim 7**, Ocel teaches an electrode configuration wherein a cylindrical electrode closes the lumen of the shaft tube into its proximal blind hole which is open to the lumen of the shaft tube as shown below. Furthermore, the electrode configuration includes three radial discharge openings extending radially from the circumflex of the electrode into the blind hole.



**Fig. 6**

**As to claim 10**, Olcel teaches that the handle is preferably made of suitable polymers including rigid plastics (§ 32).

**As to claim 12**, Olcel does not expressly disclose that the cladding is the same material (plastic) as the handle. However, Olcel included plastics as one of many non-conductive, insulating materials for the handle portion of the device. Thus Olcel had many choices for non-conductive materials and it would have been obvious to one of ordinary skill in the art at the time of the invention to implement both a plastic handle and plastic insulating cladding since it is a matter of preference.

7. **Claim 2** is rejected under 35 U.S.C. 103(a) as being unpatentable over PG Pub. No. 20030144656 to Ocel, et al., in view of U.S. Patent No. 5,944,715 to Goble, et al., as applied to claim 1 above, and further in view of U.S. Patent No. 5,634,921 to Hood, et al.

**As to claim 2**, Ocel does not expressly teach that the electrode is connected to the shaft tube by means of an axial plug-in detent. However, the means of connection between the electrode and shaft tube can be done in many different ways known by those of ordinary skill in the art. For example, Hood teaches a surgical device with an electrode tip that has an axial plug-in detent 290 to connect the distal electrode portion to the proximal portion of the device (Fig. 18, col. 11, lines 19-20). It would have been obvious to one of ordinary skill in the art at the time of the invention to connect the electrode to the shaft tube by means of an axial plug-in detent because it is an art recognized effective means for mechanically connecting two parts.

8. **Claim 11** is rejected under 35 U.S.C. 103(a) as being unpatentable over PG Pub. No. 20030144656 to Ocel, et al., in view of U.S. Patent No. 5,944,715 to Goble, et al., as applied to claim 10, and further in view of U.S. Patent No. 6,402,750 to Atkinson, et al.

**As to claim 11**, Olcel teaches that the handle 20 may include a grip portion 24. It is in the form of a pen grip since it is circular in cross section (wraps around the device). Olcel does not expressly teach that the grip is directly molded onto the shaft tube. However, a molded grip on the shaft of an article to improve manual grip is a common practice, as seen in golf clubs, ski poles, and also on surgical devices. For example, Atkinson teaches a surgical device with an injection molded grip on the shaft of the device (col. 21, lines 2-4; figure 14A). Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to directly mold the grip onto the shaft tube since molding grips onto shafts is a common method of implementing a grip onto a shaft as seen in the surgical device of Atkinson..

9. **Claim 13** is rejected under 35 U.S.C. 103(a) as being unpatentable over PG Pub. No. 20030144656 to Ocel, et al., in view of U.S. Patent No. 5,944,715 to Goble, et al., as applied to claim 1 above, and further in view of U.S. Patent No. 6,053,172 to Hovda, et al.

**As to claim 13**, the previous references do not expressly teach that the distal end of the shaft tube with the electrode is angled between approximately 30 degrees and 45 degrees with respect to the centerline of the shaft tube.

However, Hovda teaches a similar device with a shaft at a 10-30 degree angle to the distal tip may be useful for accessing tissue near or in the front portion of the mouth or nose. Furthermore, Hovda teaches that the distal portion of shaft is preferably bent to improve access to the operative site of the tissue being treated and is preferably about 30 to 60 degrees and more preferably about 45 degrees.

Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to make the angle between the distal end of the shaft tube of Ocel and the center line of the shaft tube of Ocel between 30 degrees and 45 degrees in order to improve access to tissue in regions such as the mouth or nose.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN LEE whose telephone number is (571)270-1407. The examiner can normally be reached on M-F 7:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on 571-272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/B. L./ 6/5/2009  
Examiner, Art Unit 4137

/Sam Chuan C. Yao/  
Supervisory Patent Examiner, Art Unit 4111